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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,357	05/09/2002	Bernd Ibscher	0273-0009	1386

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,357	IBSCHER ET AL.	
	Examiner	Art Unit	
	Gollamudi S Kishore, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 24-55 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6-4-2002</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The change of address dated 2-13-04 is acknowledged.

Claims included in the prosecution are 24-55.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 42-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites several active agents along with 'nose drops' as Markush members, which is improper.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 24-33, 36-38, 40, 42, 47-52 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 4021082 of record.

DE discloses skin treatment compositions containing liposomal gel. The gels contains a phospholipid, phosphatidylcholine (10 %),

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an alcohol (0.1-20 %), inositol (0.1 to 10 %) and the rest water. The alcohol is either a propylene glycol or glycerin or ethanol or mixtures thereof. The (note the abstract, page 4, line 56 through page 7, line 34, Examples and claims; claims 1 and 9 in particular).

5. Claims 24, 26-33, 36-37, 42 and 44-55 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 158 441 of record.

EP discloses compositions containing 45 % lecithin, 36 % ethylene glycol or propylene glycol and 0.9 % glucose. EP also teaches the use of phosphate buffer of pH 7.4 and the preparation is done in N₂ atmosphere. The drugs taught are insulin (abstract, page 10, lines 11-22; page 12, lines 18-31; page 13, line 34 through page 14, line 34; Examples, examples 16 and 18 in particular).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 24-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 4021082 cited above.

As discussed above, DE discloses skin treatment compositions containing liposomal gel. The gels contains a phospholipid, phosphatidylcholine (10 %), alcohol (0.1-20 %), inositol (0.1 to 10 %) and the rest water. The alcohol is either a propylene glycol or glycerin or mixtures thereof. The (note the

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abstract, page 4, line 56 through page 7, line 34, Examples and claims). DE does not teach all of the claimed ranges for the components. In the absence of showing unexpected results, it is deemed obvious to one of ordinary skill in the art to vary the ratios taught by DE to obtain the best possible results with the guidance provided by DE. DE does not appear to teach the additional amounts of glycerol or ethanol as in instant claims. However, in the absence of showing the criticality, in view of its teachings of the use of mixtures, it is deemed obvious to one of ordinary skill in the art to manipulate the basic teachings of DE to obtain the best possible dissolution of an active agent and to obtain the best possible results. Such a skill is within the skill of the art. DE does not appear to teach the use of buffers. However, since the appropriate pH conditions are desirable to prevent the adverse side effects of a composition on the skin when used topically, it is deemed obvious to one of ordinary skill in the art to use buffers. Although the method of preparation described by DE is by mixing the components together it does not appear to teach the mixing to be done in an inert atmosphere. However, it is within the skill of the art to recognize that phospholipids are susceptible to oxidation and therefore, the mixing has to be done in an oxygen free atmosphere if the phospholipids are unsaturated.

8. Claims 39 and 42-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 4021082 cited above in combination with EP 0158 444 cited above.

The teachings of DE have been discussed above. What are lacking in the teachings of DE are the explicit teachings of the use of a buffer and the use of an inert atmosphere to prepare the phospholipid formulations.

EP as discussed above, while disclosing phospholipid containing liposome preparations teaches the use of appropriate buffer with a pH ranging from 3.2-8.6 in combination with a labile active agent such as insulin. The phospholipids can either be lecithin (unsaturated) or dipalmitoylphosphatidylcholine (saturated). EP also advocates the use of an inert atmosphere (nitrogen) while preparing lecithin formulations (abstract, page 5, lines 24-25; page 10, lines 11-22; page 12, lines 18-31; page 13, line 34 through page 14, line 34). It would have been obvious to one of ordinary skill in the art to use appropriate buffers when used in combination with labile drugs such as insulin and use an inert atmosphere while preparing the compositions as evident from EP and from the guidance provided by EP with a reasonable expectation of success. The use of hydrogenated phosphatidylcholine instead of unsaturated compound, with a reasonable expectation of success, would have been obvious to one of ordinary skill in the art since EP advocates such a use.

The examiner requests an English translation of the reference in order to reconsider the rejections made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK